

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of TECAR Therapy on Pain Relief, Functional Disability and Range of Motion in Patients with Non-specific Chronic Low Back Pain

#### Protocol summary

##### Study aim

The Effect of TECAR Therapy on Pain Relief, Functional Disability and Range of Motion in Patients with Non-specific Chronic Low Back Pain

##### Design

The sampling method in this study is of an unpredictable type available in the form of easy sampling from people who are available in the community to the examiner. The method of grouping is randomized to one person, in which, after the initial examination, using Excel software, the subjects are in one of two groups of 1 or 2; group 1, the group under the usual treatment of physiotherapy In group 2, the group is under treatment with regular treatment with physiotherapy.

##### Settings and conduct

First, volunteers are checked for entry and exit criteria. Then, in order to observe ethical points of view, the objectives, methodology and conditions of the test will be fully explained to eligible individuals. If people are willing to participate in the study, informed consent is obtained from the project. Prior to conducting the main study, a preliminary study is conducted to examine the relative and absolute repeatability of the information collected by a test. To measure dependent variables such as pain intensity, range of motion, functional disability, all conditions are quite similar to The main study will be done. In order to measure the severity of pain, the VAS index is used for assessing functional disability. The Oswestry and Roland-Mauritius questionnaires are not used. Repeatability is not required. Inclinator meter is used to measure the range of motion. In order to verify its repeatability, the amplitude Flexion, extension and side bending 8 to 10 subjects are first examined during the initial examination, and the second time, 15 to 20 minutes after the examination and before the treatment, and the correlation between the numbers obtained for each We will examine the person.

##### Participants/Inclusion and exclusion criteria

Entry requirements: women and men between 20 and 60 years, history of back pain for more than 3 months, or at least half a day in the last 6 months, pain intensity greater than 3 based on VAS index, no acute and inflammatory back pain, subacute and tracheostomy back pain Lack of spinal cord stenosis, scoliosis and ankylosing spondylitis, lack of postpartum back pain or pregnancy, no history of bone surgery, fractures of the lower back, osteoporosis, infection, cancer, neurological diseases, etc., having no history of any treatment Physiotherapy for the waist during the past month Exit criteria: The use of medication during the study, the unwillingness of the participant to continue the treatment, have been trained in exercises other than those during the course of the treatment.

##### Intervention groups

Participants are grouped randomly in two different therapeutic groups, a group treated with TECAR and a group treated with usual Physical Therapy.

##### Main outcome variables

severity of pain, functional disability, range of motion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171224038043N1**

Registration date: **2018-01-24, 1396/11/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-24, 1396/11/04**

Update count: **0**

##### Registration date

2018-01-24, 1396/11/04

##### Registrant information

##### Name

Mozhdeh Dariush

##### Name of organization / entity

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 7750 6157

**Email address**

mo.dariush@uswr.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source****Expected recruitment start date**

2018-01-13, 1396/10/23

**Expected recruitment end date**

2018-08-22, 1397/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of TECAR Therapy on Pain Relief, Functional Disability and Range of Motion in Patients with Non-specific Chronic Low Back Pain

**Public title**

The Effect of TECAR Therapy on Pain Relief, Functional Disability and Range of Motion in Patients with Non-specific Chronic Low Back Pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Men and women between the ages of 20 and 60 History of back pain for more than 3 months, or at least half a day in the last 6 months Pain intensity greater than 3 according to V.A.S Not having acute and inflammatory back pain, subacute and traumatic low back pain Not having spinal canal stenosis, scoliosis and ankylosing spondylitis Not having back pain after delivery or during pregnancy Not having history of bone surgery, lumbar vertebral fracture, osteoporosis, infection, cancer, neurological diseases Not having a history of any type of physical therapy for your back during the past month

**Exclusion criteria:**

Use of medication during research Participant's reluctance to continue treatment Doing exercises other than those trained in the course of treatment

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomize Using Excel

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Individuals in each group are unaware of the existence of the other group, and those who do the treatment are not grouped and the participants in each group are unaware.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of the University of Social Welfare and Rehabilitation Sciences

**Street address**

Kodakyar Ave., Daneshjo Blvd., Evin

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Approval date**

2018-01-06, 1396/10/16

**Ethics committee reference number**

IR.USWR.REC.1396.282

**Health conditions studied****1****Description of health condition studied**

Non-specific chronic low back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

**Primary outcomes****1****Description**

Pain severity score with the V.A.S index

**Timepoint**

The beginning and the end of each treatment session and one week after the completion of the study

**Method of measurement**

V.A.S index

## 2

### **Description**

Functional disability assessment through Oswestery and Roland-morris questionnaires

### **Timepoint**

The beginning and the end of each treatment session and one week after the completion of the study

### **Method of measurement**

Oswestry and Roland-morris questionnaires score

## 3

### **Description**

Measuring the range of motion through the Inclinator tilt

### **Timepoint**

The beginning and the end of each treatment session and one week after the completion of the study

### **Method of measurement**

Inclinometer Tilometer

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: A treatment group with TECAR, 10 sessions of treatment with a TECAR machine, along with the usual treatment of physiotherapy that is exactly the same as the control group. The sessions were every other day .

#### **Category**

Treatment - Devices

### 2

#### **Description**

Control group: The usual physical therapy therapy group, 10 sessions of TENS with exercise sessions were one day and each treatment session was 30 minutes TENS (15 minutes of high frequency or TENS normal at 100 Hz and 40 microsecond pulse duration, And 15 min low frequency TENS, with a frequency of 5 Hz and a pulse duration of 300 microseconds, without special order)

#### **Category**

Treatment - Devices

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Novin Teb Physiotherapy

##### **Full name of responsible person**

Mozhdeh Dariush

#### **Street address**

First Floor ,No. 416, Abureyhan Station, Between 30 Meters Narmak and Khaghani, Damavand Avenue

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#### **Postal code**

1743795149

#### **Phone**

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#### **Email**

mozhdeh\_dariush@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

University of social welfare and rehabilitation sciences

##### **Full name of responsible person**

Iraj Abdollahi

##### **Street address**

Dead end Koodakyar, Daneshjo Boulevard, Daneshgah Square

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##### **Province**

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##### **Phone**

+98 21 2218 0083

##### **Email**

ir.abdollahi@uswr.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

No

#### **Title of funding source**

Novin Teb Physiotherapy

#### **Proportion provided by this source**

100

#### **Public or private sector**

Private

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Persons

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

University of social welfare and rehabilitation sciences

##### **Full name of responsible person**

Mozhdeh Dariush

**Position**  
student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Physiotherapy  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

### Contact

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University of social welfare and rehabilitation sciences  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

The total potential data is shared after being unidentified

### When the data will become available and for how long

Start the access period, 5 months after printing the results

### To whom data/document is available

Researchers and experts in this field

### Under which criteria data/document could be used

In order to complete the information of the researcher and carry out statistical analyzes and provide documentation on the conduct of the research approved and under the supervision of professors of the university

### From where data/document is obtainable

By email (mozhddeh\_dariush@yahoo.com), phone call (09127965250)

### What processes are involved for a request to access data/document

Submission of documentation for the research to be approved and under the supervision of university professors

### Comments